REMARKS

Claims 1, 2 and 21 are pending in the application. Claims 3-20 and 22 have been cancelled. Claims 1, 2 and 21 have been rejected.

Claim Rejections- 35 U.S.C. §103

(1.) Claim 1 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Liang *et al.* 1998, (*Infection and Immunity*, 66 (5), 1834-1838), Liang *et al.* 1997, (*Anal. Biochem.*, 250 (1), 61-65) or each in view of Harlow and Lane, (*Antibodies, A Laboratory Manual*, Chapters 5 and 6, Cold Spring Harbor Press, 1988).

According to M.P.E.P. 2143.03, all of the claim limitations must be taught or suggested by the prior art to establish *prima facie* obviousness of a claimed invention. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). Claim 1 is directed to a composition for treating an equid infected with *Sarcocystis neurona* comprising a mixture of isolated antibodies against a 16

±4 kDa antigen of *Sarcocystis neurona* and isolated antibodies against a 30 ±4 kDa antigen of *Sarcocystis neurona* wherein the antibodies are from serum of an animal immunized with the antigen and wherein the mixture is in a pharmaceutically acceptable carrier. Liang *et al.* 1998, Liang *et al.* 1997, and Harlow and Lane, either taken alone or in combination, do not show or suggest a composition having a mixture of isolated antibodies against a 16 ±4 kDa antigen and isolated antibodies against a 30 ±4 kDa antigen. Neither do the cited references show or suggest the mixture of antibodies in a pharmaceutically acceptable carrier.

Liang *et al.* 1997 teaches three proteins that were purified from *S. neurona* merozoites with molecular weights of 100, 30, and 19 kDa. Harlow and Lane teaches general methods for the production of monoclonal antibodies and polyclonal antibodies from antigens. Liang *et al.* 1998 teaches that serum and cerebrospinal fluid (CSF) from horses with a clinical diagnosis of a neurologic disorder resembling equine protozoal myeloencephalitis (EPM) reacted with combinations of Sn30, Sn16, Sn14, and Sn11 proteins from *Sarcocystis*

neurona (*S. neurona*) to form various band patterns on an immunoblot. The serum and CSF samples were grouped together by Liang *et al.* 1998 based upon the resulting band patterns. Liang *et al.* 1998 then teaches that *in vitro* neutralization assays against *Sarcocystis neurona* merozoites isolated from bovine turbinate cell culture revealed "significant differences in inhibitory activities between the groups of serum and CSF samples with different immunoblot band patterns" (Liang *et al.* 1998: page 1837, first full paragraph.) However, when Liang *et al.* 1998 correlated band patterns with inhibitory activities it was concluded that no inhibitory activity correlating with the antibody to Sn30 (the 30 kDa protein) was noted. (Liang *et al.* 1998: page 1836, first paragraph; Sn30 is a 30 kDa protein as noted in the first paragraph, "Immunoblot band patterns", on page 1835.) This can be clearly seen with sample N6 which recognizes the Sn30 protein of *Sarcocystis neurona*. (Liang *et al.* 1998: Figure 2 on page 1836). Therefore, a person of skill in the art would not be motivated to provide a composition having a mixture of isolated antibodies against a 16 ±4 kDa antigen and isolated

antibodies against a 30 ±4 kDa antigen. Furthermore, a person of skill in the art would have no motivation to provide a composition with the mixture of antibodies in a pharmaceutically acceptable carrier.

The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). None of the cited references would motivate a person of skill in the art to combine the teachings of the cited references. In addition, according to Liang *et al.* 1998, "[a]ntibodies to Sn30 are not recognized as specific since a 30-kDa antigen immunoreactive with sera from horses with EP is found in other *Sarcocystis* spp." (Liang *et al.* 1998: page 1837, column 1, first full paragraph). Since Liang *et al.* 1998 actually teaches that the Sn30 antibodies are not even recognized as being specific for the 30 kDa antigen from *Sarcocystis neurona*, there would be no reason to believe that the Sn30 antigen is important for immunity. The serum antibodies from horses with EPM are known to also react with a 30 kDa antigen from other

Sarcocystis spp. A person of skill in the art, armed with such knowledge, would not be motivated to make the claimed composition. Therefore, the claims are not obvious over Liang *et al.* 1998, Liang *et al.* 1997, and Harlow and Lane. Reconsideration of the rejection is requested.

(2.) Claim 21 and 2 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Liang *et al.* 1998, (*Infection and Immunity*, 66 (5), 1834-1838), Liang *et al.* 1997, (*Anal. Biochem.*, 250 (1), 61-65) each in view of Harlow and Lane, (*Antibodies, A Laboratory Manual*, Chapters 5 and 6, Cold Spring Harbor Press, 1988).

According to M.P.E.P. § 2142, "[t]o establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all of

the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Liang *et al.* 1997 teaches three proteins that were purified from *S. neurona* merozoites with molecular weights of 100, 30, and 19 kDa. Harlow and Lane teaches general methods for the production of monoclonal antibodies and polyclonal antibodies from antigens. Liang *et al.* 1998 teaches that surface proteins Sn14 and Sn16 of *Sarcocystis neurona* merozoites are involved in infection and immunity. Liang *et al.* 1998, Liang *et al.* 1997, and Harlow and Lane, either taken alone or in combination, do not provide motivation to one of ordinary skill in the art to provide a method for treating an equid infected with *Sarcocystis neurona* by inoculating a mixture of antibodies against a 16 ±4 kDa antigen and a 30 ±4 kDa antigen of Sarcocystis neurona as claimed in Claims 21 and 2.

A prior art reference must be considered in its entirety, *i.e.*, as a whole, including portions that would

lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984). Therefore, it is improper to combine references where the references teach away from their combination. *In re Grasselli*, 713 F.2d 731, 743, 218 USPQ 769, 779 (Fed. Cir. 1983). Liang *et al.* 1998 teaches away from a method for treating an equid infected with *Sarcocystis neurona* by inoculating a mixture of antibodies against a 16 ±4 kDa antigen and a 30 ±4 kDa antigen of *Sarcocystis neurona* as claimed in Claims 21 and 2. According to Liang *et al.* 1998, "[n]eutralization assays revealing significant differences in inhibitory activities between the groups of serum and CSF samples with different immunoblot band patterns strongly suggest that antibodies specific for Sn14 and Sn16 have protective activity against *S. neurona*, at least in vitro (Fig. 1 and 2) and support the use of the immunoblot test in diagnosis of EPM. Antibodies to Sn30 are not recognized as specific since a 30-kDa antigen immunoreactive with sera from horses with EPM is found in other *Sarcocystis* spp." (Liang *et al.* 1998: page 1837, column 1, first full

paragraph). Nothing in the references suggest that the Sn30 would be of interest, since Liang *et al.* 1998 actually teaches that the Sn30 antibodies are not even recognized as being specific for the 30 kDa antigen from *Sarcocystis neurona*. The serum antibodies from horses with EPM are known to also react with a 30 kDa antigen from other *Sarcocystis* spp. Armed with this knowledge, one of ordinary skill in the art would not have been motivated to treat an equid infected with *Sarcocystis neurona* by the method set forth in Claims 21 and 2.

Liang *et al.* 1998 would actually lead a person of ordinary skill in the art away from the claimed invention, since *in vitro* neutralization assays against *Sarcocystis neurona* merozoites show that the Sn30 antigen provides no inhibitory activity. Therefore, Liang *et al.* 1998, Liang *et al.* 1997, and Harlow and Lane, either taken alone or in combination, do not provide motivation to one of ordinary skill in the art to a method for treating an equid infected with *Sarcocystis neurona* by inoculating a mixture of antibodies against a 16 ±4 kDa antigen and a 30 ±4 kDa antigen of Sarcocystis neurona as claimed in Claims 21 and 2.

In the claimed method, an equid is inoculated with a mixture of antibodies against a 16 ±4 kDa antigen and a 30 ±4 kDa antigen, both of which are specific to *Sarcocystis neurona*, wherein the antibodies are selected from the group consisting of polyclonal antibodies from serum from an animal immunized with the antigen and monoclonal antibodies from a hybridoma, and wherein the antibodies are in a pharmaceutically acceptable carrier. The cited references do not teach or suggest all of these limitations of the claimed method. None of the cited references teach using the mixture of antibodies, including antibodies against the 30 kDa antigen, with or without a pharmaceutically acceptable carrier. The cited references, either taken alone or in combination, do not show or suggest the method claimed by Applicants. Thus, it appears that this is an improper rejection based upon impermissible hindsight reasoning. The references must be viewed without the benefit of impermissible hindsight vision. *Hodosh v. Block Drug Co., Inc.*, 786 F.2d 1136, 1143 n.5, 229 USPQ 182, 187 n.5 (Fed. Cir. 1986). Therefore, the claims are not obvious over the cited references. Reconsideration of the rejection is

requested.

In light of the above, it is now believed that Claims 1, 2 and 21 are patentable and in condition suitable for allowance. Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

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